**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCT LIABILITY LITIGATION

MDL No. 02419
Docket No. 1:13-md-2419-RWZ

*This document relates only to*:

*Armetta*, No. 1:14-cv-14022-RWZ
*Bowman*, No. 1:14-cv-14028-RWZ
*Davis*, No. 1:14-cv-14033-RWZ
*Dreisch*, et al. No. 1:14-cv-14029-RWZ
*Farthing*, No. 1:14-cv-14036-RWZ
*Kashi*, No. 1:14-cv-14026-RWZ
*Torbeck*, No. 1:14-cv-14023-RWZ
*Handy* No. 1:14-cv-14019-RWZ

**PLAINTIFFS' RESPONSES TO BOX HILL DEFENDANTS' STATEMENT OF UNDISPUTED MATERIAL FACTS IN RELATION TO ITS CONSOLIDATED MOTION FOR PARTIAL SUMMARY JUDGMENT**

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**Notice**: During the September 21, 2017 MDL 2419 status hearing the Court extended the deadline for Plaintiffs' to file their oppositions to Defendants' motions for summary judgment to October 16, 2017.

Plaintiffs, through undersigned counsel, respond herein pursuant to Federal Rule of Civil Procedure 56 of Civil Procedure and L.R. D. Mass. 56.1 to Defendants Box Hill Surgery Center, L.L.C., Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, L.L.C. (hereinafter, collectively "Defendants," "Box Hill Defendants," or "Box Hill"), Statement of Undisputed Material Facts.

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| 1. The Plaintiffs' alleged injuries and causes of action arise from the fungal meningitis outbreak caused by contaminated, preservative-free, methylprednisolone acetate ("MPA") manufactured and sold by the New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC").[2]<br><br>[1] Dreisch Complaint at 3, ¶ 1. | **Disputed**.<br><br>Misstates the record. The purported fact omits and ignores the nature of the claims being asserted against the Box Hill Defendants.<br><br>In addition to the Box Hill Defendants' ordering, receiving, and administering contaminated MPA sold and dispensed by NECC in violation of Massachusetts and Maryland prescription medication laws, Plaintiffs alleged and during discovery have marshaled record proof supporting causes of action against the Box Hill Defendants based upon numerous actionable failures to meet minimum standards of medical care regarding:<br><br>1) Medical decision-making on whether the use and administration of "preservative-free" compounded MPA was a better, safer alternative steroid medication than manufactured MPA available from FDA licensed, approved, and inspected manufacturers for administration to specific Box Hill patients (including each Plaintiff) based upon their particular medical situation and needs;[1*] |

[1] Box Hill's footnotes are denoted with a superscript number (e.g.- "[1]") and appear at the end of each table cell.

[2] Plaintiffs footnotes are denoted with a superscript number and asterisk (e.g.- "[1*]") and appear at the end of each table cell.

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| | 2) The selection of Box Hill's provider of sterile compounded medical preparations being injected into Box Hill patients;[2*]<br>3) The administration of compounded "preservative-free" MPA to multiple patients drawn from 5 ml *single use* vials in contravention of professional medication safe use standards;[3*]<br>4) Defendants' inadequate and erroneous clinical understanding of the differences and increased risks, including contamination, of using mass compounded drug preparations for injection in their patients;[4*]<br>5) Defendants' not informing Box Hill patients (including Plaintiffs) that they would be administered non-FDA regulated mass compounded preservative free MPA (that turns out actually was not totally preservative-free as NECC's contained polyethylene glycol-"PEG"- a preservative associated in some medical literature with MPA side effects), and of the increased risks associated with compounded preparations when compared to those manufactured by FDA approved manufacturers. [5*]<br>Plaintiffs' three common issue liability experts' opinions establish that the Box Hill Defendants lacked material requisite fundamental professional knowledge a medical care provider reasonably should possess concerning pharmaceutical compounded preparations and violated applicable standards of care in numerous ways:<br>• *Dr. Shmuel Shoham, M.D.*, Associate Professor of Medicine at Johns Hopkins University School of Medicine has opined: |

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| | "Under Maryland's law applicable to prescribing prescription medicines, as well the applicable standards of care on prescribing and administering prescription medications, a doctor must prescribe a prescription medication that is to be filled and dispensed by a pharmacy – which includes compounding pharmacies when prescribing a compounded medication – only for a specific patient that he or she is treating and for a specific medical need of that particular patient. Dr. Bhambhani failed to do this. Additionally, once a prescription medication is dispensed with a label identifying it as prescribed for a specific patient, a doctor (or clinical staff at his or her direction) may not transfer that medication and administer it to a different person or patient."[6*]<br><br>• *Dr. Lloyd R. Saberski, M.D.*, Assistant Clinical Professor Internal Medicine, Yale University (board certified anesthesiology and pain management medicine) opines and explains:<br><br>"If a physician wants a product from a compounding pharmacy, it must be because he or she is treating a patient with a specific need that cannot be fulfilled by a FDA approved manufactured product. If there are FDA approved products that can fulfill the need, then there would be no need for compounding a product. In this group of cases Dr. Bhambhani and Box Hill Surgery Center utilized a NECC compounded MPA which was benzyl alcohol-free when there were FDA approved benzyl alcohol-free deposit steroids available. Thus, |

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| | there was no need to even consider the use of a compounded steroid preparation, [and] doing so in my opinion violated the standard of care applicable both to prescribing physicians and ambulatory care/procedure clinic."<br><br>"If Dr. Bhambhani and Box Hill Surgery Center had a legitimate medical or scientific reason for ordering compounded MPA from NECC (which in my opinion they did not), they were required under Maryland and Massachusetts law to write a prescription specific for their patient and their patient's special needs. Dr. Bhambhani never wrote a prescription for MPA for any particular patient with a patient-specific special need, which was a violation of the applicable standards for working with compounding pharmacies."<br><br>"Another wrong and troubling action was Box Hill's and Dr. Bhambhani's purchasing MPA for a particular patient and administering the MPA to a different patient. The MPA that was made available to Dr. Bhambhani and Box Hill Surgery Center from NECC was shipped in bulk quantities, was not patient specific and did not have any specification for patient special needs."<br><br>"There also is no indication Dr. Bhambhani prior to the infection outbreak in 2012 discussed with this group of Box Hill Surgery Center patients the fact she was administering a steroid medication that was made by a compounding pharmacy and the risks and benefits |

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| | of using a compounded and not FDA approved manufactured steroid product. It is likely that Dr. Bhambhani did not discuss the fact that she was administering compounded medication with her patients because she mistakenly thought NECC compounded products were FDA approved. This erroneous understanding is inexcusable and denied her patient the opportunity to give an informed consent to the procedures."[7*]<br><br>• *David Chason, RPh, MBA*, former Commissioner of Maryland Board of Pharmacy noted:<br><br>"The lack of knowledge about compounding practices and failure to adhere to good operational and clinical practice relating to pharmaceuticals by Dr. Bhambhani and her staff, however, provides the basis to conclude that had Dr. Bhambhani known and followed laws and regulations regarding the rules for writing prescriptions, understood the differences between compounding and manufacturing, done the appropriate amount of due diligence on the choice of vendors, and followed appropriate procedures for handling, storage and use of vials of preservative-free MPA, her patients would not have been placed at risk of serious infection in 2012."[8*]<br><br>---<br><br>[1*] Ex. 1 (September 11, 2016 Expert Report of Lloyd R. Saberski, M.D.) at 2-3, Ex. 2 (January 12, 2017 Deposition of Lloyd R. Saberski, M.D.) at 78:3-81:1; 85:10-90:15, Ex. 3 (September 14, 2016 Expert Report of Shmuel Shoham, M.D.) at 2-3, Ex. 4 (January |

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| | 19, 2017 Deposition of Shmuel Shoham) at 42:11-43:18.<br><br>[2*] Ex. 1 at 2-3, Ex. 2 at 56:8-20, 103:14-104:12, 147:22-148:11, 153:3-13, Ex. 5 (December 21, 2016 Deposition of David Chason) at 163:10-164:16; 175:20-177:9; 201:7-202:7.<br><br>[3*] Ex. 1 at 4, Ex. 2 at 109:13-111:21; 112:9-113:20; 118:3-13, Ex. 6 (September 13, 2016 Expert Report of David Chason) at 6-7; Ex. 5 at 209:7-15; 210:4-211:10, Ex. 3 at 3, Ex. 4 at 108:6-109:9; *see also CDC's Position — Protect Patients Against Preventable Harm from Improper Use of Single-dose/Single-use Vials*, Center for Disease Control and Prevention, https://www.cdc.gov/injectionsafety/cdcposition-singleusevial.html (last visited October 16, 2017).<br><br>[4*] Ex. 2 at 78:3-79:12; 103:7-10.<br><br>[5*] Ex. 1 at 5, Ex. 2 at 190:1-192:15.<br><br>[6*] Ex. 3 at 3.<br><br>[7*] Ex. 1 at 2-3, 3, 4.<br><br>[8*] Ex. 6 at 2. |
| 2. The tainted vials were limited to those in certain lots: Lot # 05212012@68 (BUD 11/17/2012); Lot # 06292012@26 (BUD 12/26/2012); and Lot # 081029[sic-0]12@51 (BUD 2/6/2013).[2] However, not every vial in each lot was contaminated.<br><br>———————<br><br>[2] Dreisch Complaint at 17, ¶ 51. | **Undisputed.** |

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| 3. Dr. Bhambhani administered MPA in vials from Lot # 05212012@68 and Lot # 6292012@26 while performing epidural steroid injection procedures.[3]<br><br>_____<br><br>[3] Dreisch Complaint at 37, ¶ 145. | **Undisputed.** |
| 4. Dr. Bhambhani and the Box Hill Defendants purchased preservative-free MPA from NECC because her previous employer used it, she had good results with it, and she was concerned about adverse events caused by preservatives.[4]<br><br>_____<br><br>[4] Dr. Bhambhani Dep. Trans. at 71:25-73:16. | **Disputed.**<br><br>Defendants' statement of fact is based solely upon Dr. Bhambhani's uncorroborated self-serving testimony which opens up questions regarding her credibility. It also misstates the record as it omits material facts necessary to place and evaluate these alleged facts in proper context.<br><br>To the extent Dr. Bhambhani's testimony is credited, it evidences how little, indeed virtually nothing, was done by her and the Box Hill Defendants to select and vet NECC as well as determine the appropriateness of a general practice of using a preservative-free MPA preparation—let alone a preservative free compounded version—secured from a sight unseen pharmacy located hundreds of miles away.[9*]<br><br>MPA is a difficult and highly risky drug preparation to make aseptically. Making a version without preservatives increases the risk of contamination, calling for heightened vigilance in determining the source, purity, and potency of the preparation.[10*]<br><br>For example, beyond an apparently brief discussion with a peer doctor she worked with at a medical facility, Dr. Bhambhani made no inquiry whatsoever into NECC's qualifications beyond getting its name and contact information from an administrative person at her then current employer (Harford County Ambulatory Surgery Center). In connection |

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| | with obtaining MPA from NECC she neither asked for nor received any documentation on the purity and potency of the preparation. She neither inspected the facility herself (one of the ways to vet a compounding pharmacy as a source) nor spoke to anyone locally in NECC's area regarding NECC's facilities and qualifications, which could have been readily done by simply obtaining local area references. Nor when Dr. Bhambhani was confronted with the red flag of being instructed to provide names of prior patients in order to obtain supplies of MPA in five (5) 5ml vials per listed name quantities, did she, as she should have, consider whether something was amiss, whether this was appropriate medical practice on her part and her clinic's part, or whether this was consistent with prescription drug law; which on all scores it was not.[11*]<br><br>Moreover, Dr. Bhambhani read absolutely zero medical literature on MPA and its use for epidural steroid injection procedures or on the risks and benefits of using MPA with preservatives versus MPA that was preservative free. That she had allegedly used NECC's medication in the past without incident proves nothing more than her and her co-defendants' fortuitous good luck prior to the summer of 2012, given what was risked by ordering and administering NECC's preservative-free MPA preparation in blind faith, along with her and NECC's gross short circuiting of rudimentary drug prescription practices.[12*]<br><br>Further, it is inaccurate to say that Dr. Bhambhani changed to a preservative-free steroid because she had become concerned about preservatives in corticosteroids. It appears she chose to change just by happenstance when it was recommended she try preservative-free MPA during a chat with a colleague who was using it. She had |

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| | experienced some complications with the administration of other corticosteroids. It was her belief that they were known side effects from the steroids themselves rather than any preservative in the steroid. She could have accomplished the same goal of eliminating benzyl alcohol from the corticosteroid by simply ordering 1 ml. vials from a manufacturer.[13*]<br><br>In the end, the alleged facts, even if proven, do no more than prove the Box Hill Defendants' liability for unwarranted, wrongful and negligent blind faith decisions concerning the use of NECC's preservative-free MPA for its epidural steroid injection procedures.<br><br>_____<br><br>[9*] Ex. 7 (February 10, 2016 Deposition of Ritu Bhambhani, M.D.) at 71:21-73:1, 74:13-77:8,79:22-81:10, Ex. 2 at 78:3-81:1; 86:5-89:3; 99:3-15; 103:14-104:12; 121:19-122:9, Ex. 5 at 175:20-177:9; 178:19-179:1.<br><br>[10*] Ex. 2 at 107:16-110:20; 182:13-183:14.<br><br>[11*] Ex. 7 at 84:6-87:2; 99:23-100:11; 115:14-117:5.<br><br>[12*] Ex. 7 at 79:22-80:16, Ex. 2 at 133:15-21; 153:2-13; 135:3-136:1; 154:3-155:4, Ex. 5 at 175:20-177:9.<br><br>[13*] Ex. 7 at 75:1-77:21, Ex. 2 at 182:13-184:3. |
| 5. Similarly, thousands of health care providers across the country purchased drugs from the New England Compounding Center ("NECC") even in just the five months preceding the meningitis outbreak at issue.[5] There were certainly more health care providers who purchased NECC's MPA prior to May 2012. | **Disputed.**<br><br>It is misleading for Defendants to say that thousands of health care providers ordered drugs from NECC in the five months preceding the meningitis outbreak. According to the document Box Hill refers to, only 91 health care providers purchased preservative- |

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| _____<br><br>[5] *See* NECC Customer List Since 5/21/2012, attached as **Exhibit 2**. | free MPA corticosteroids from NECC during this time period.[14*]<br><br>The relative risks as to the purchase of other drugs, for example, topical creams, is obviously not the same for sterile drug preparations that are injected into a patient's epidural space.<br><br>In the 2012 meningitis outbreak, 76 clinics/hospitals across the United States injected patients with one of the three contaminated lots of MPA. Seven (7) of the clinics, including Defendants', were located in Maryland.[15*]<br><br>Even so, what other healthcare providers across the country did is irrelevant both generally and specifically as Dr. Bhambhani neither knew nor relied upon what these other doctors allegedly did when choosing to use preservative-free steroids on her patients, and in selecting NECC as the source to purchase the MPA.[16*]<br><br>_____<br><br>[14*] *See* NECC Customer List Since May 21, 2012, Attached as Exhibit 2 to Defendants' Statement of Undisputed Material Facts in Relation to Consolidated Motion for Partial Summary Judgment.<br><br>[15*] *See Multistate Fungal Meningitis Outbreak Investigation – Case Count, Centers for Disease Control and Prevention*, at *https://www.cdc.gov/hai/outbreaks/meningitis-map-large.html*.<br><br>[16*] Ex. 7 at 99:23-100:11. |

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| 6. NECC was regulated and inspected by the U.S. Food and Drug Administration ("FDA").[6] In a letter to Mr. Cadden and NECC dated December 4, 2006, the FDA affirmed its position that "the Federal Food, Drug, and Cosmetic Act ("FDCA") establishe[d] agency jurisdiction over 'new drugs,' including compounded drugs."[7]<br><br>[6] *See* FDA Warning Letter, attached as **Exhibit 3**.<br><br>[7] *Id.* | **Disputed**.<br><br>Misstates the record evidence regarding the differences between FDA oversights on the manufacture of drugs versus compounding of substances by compounding pharmacies, and ignores statutory and regulatory prohibitions against mass compounding medications.[17*]<br><br>[17*] Ex. 2 at 86:5-16; 134:9-135:18; 182:13-183:14, Ex. 5 at 163:2-164:16; 176:7-177:9. |
| 7. In addition to such regulatory oversight, NECC also passed the inspection of the Massachusetts Board of Registration in Pharmacy about a year prior to the outbreak, as well as an inspection by Brigham and Woman's [sic] Hospital, a highly accredited and respected healthcare institution, as recently as a week prior to the time that the first batch of recalled MPA solution was manufactured in May 2012.[8]<br><br>[8] *See* Commonwealth of Massachusetts Inspection Report, attached as **Exhibit 4**; Brigham and Women's [sic] Hospital Department of Pharmacy USP <797> Audit of NECC, attached as **Exhibit 5**; Brigham and Women's [sic] Vendor Audit Survey Form, attached as **Exhibit 6**. | **Disputed.**<br><br>Misstates the record and is also irrelevant as:<br><br>(1) Dr. Bhambhani did no investigation whatsoever into any inspections of NECC or any facility that used NECC's compounded products;[18*] and<br><br>(2) The Brigham and Women's Hospital May 2012 inspection was remarkably flawed as it failed to conform to its own inspection protocols. Among other things, the inspection was not unannounced and the inspectors failed to enter and inspect the clean rooms. Indeed, the inspection was more one of going through the motions to satisfy upcoming accreditation committee survey questioning than a *bona-fide* inspection to determined NECC's suitability as a vendor of "high risk" sterile compounded medications under USP <797>.[19*]<br><br>As to the Massachusetts Board of Registration in Pharmacy May 24, 2011 inspection, this likewise was also flawed and inadequate in that, *inter alia,* it was announced, the inspector did not enter the clean room and environmental monitoring records were not looked at. The inspection was perfunctory and done at a time when the pharmacy was not |

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| | operational as it was conducted in response to a notice of renovation and expansion in contrast to a complaint filed with the FDA. Moreover, no additional inspections, were done until after the fungal meningitis outbreak.[20*]<br><br>[18*] Ex. 7 at 84:6-87:2; 99:23-100:11; 115:14-117:5.<br><br>[19*] Ex. 2 at 146:7-15, Ex. 8 (June 4, 2015 Deposition of Michael Cotugno) at 83:12-84:23; 166:7-167:2; 173:22-174:4; 178:1-9; 181:19-183:17; 191:12-192:10; 193:10-197:13; 219:13-220:12, Ex. 9 (June 3, 2015 Deposition of Francis McAteer) at 190:9-17; 199:15-200:20; 201:17-203:12; 221:22-222:11; 227:8-14; 267:15-19.<br><br>[20*] Ex. 10 (December 4, 2015 Deposition of Samuel Penta) at 34:6-19; 35:8-38:19; 45:4-20; 306:15-311:6. |
| 8. After receiving orders from healthcare providers like Dr. Bhambhani, NECC failed to "follow either the proper USP 797 autoclaving sterilization procedure or its own standard operating procedure," failed to take action on at least twenty-six occasions between January 2012 and September 2012 despite results from an internal environmental monitoring program that recorded bacteria and mold in the clean rooms used to produce "sterile" drug products, and distributed two lots of the recalled MPA before receiving results from sterility testing.[9]<br><br>[9] Dreisch Complaint at 20, ¶ 66; *Id*. at 22, ¶ 81; *Id*. at 19, ¶ 64 | **Disputed**.<br><br>Box Hill responded to ¶¶ 64, 66, and 81 of Plaintiff Dreisch's Complaint it cites as basis with the following denial: "The Box Hill Defendants lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein." It remarkably now solely relies upon these denied allegations. The allegation therefore does not suffice in presenting an undisputed and indisputable fact.<br><br>To the extent the allegation implies the compounded MPA Box Hill received from NECC was compounded in response to and following Bhambhani's prescriptions (which were not mere purchase "orders" but, rather, were drug prescriptions for identified patients), the MPA vials dispensed by NECC |

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| | was actually mass produced by NECC prior to Box Hill's receipt of Box Hill's prescription. |
| 9. The parties are in agreement that the applicable standard of care and professional practice did not require the Box Hill Defendants to travel to the NECC facility to perform an inspection prior to purchasing medications from NECC.[10]<br><br>_____<br><br>[10] *See* Deposition Transcript of Dr. Lloyd R. Saberski, 67:7–67:10, excerpts attached as **Exhibit 7**; *see also* Deposition Transcript of Dr. Laxmaiah Manchikanti, 104:10–105:6, excerpts attached as **Exhibit 8**. | **Undisputed**, **contingent upon the qualifications** that (1) the applicable standard of care required Defendants to reasonably investigate the supplier they chose to purchase steroids from when deciding to use a compounded pharmacy as source in order to assure patient safety (as well as efficacy) in the use of compounded medications for injection into or near patients' spinal cord, and (2) conducting appropriate inspections is one way the standard can be complied with.<br><br>Importantly, Defendants according to the record did absolutely nothing to comply with the standard of care to properly ascertain the abilities and reliability of NECC as a source for high risk compounded sterile injectable preparations such as preservative-free MPA.<br><br>This contention is also disputed because of the use of the term "standard of professional practice."[21*]<br><br>_____<br><br>[21*] Ex. 7 at 71:21-73:1, 74:13-77:8,79:22-81:10; 87:11-89:25, Ex. 1 at 2, Ex. 2 at 56:8-20, 103:14-104:12, 147:22-148:11, 153:3-13, Ex. 5 at 163:10-164:16; 175:20-177:9; 201:7-202:7. |
| 10. On March 22, 2017, Barry Cadden, the owner and head pharmacist of NECC, was convicted by a federal jury of racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead in connection with the 2012 nationwide fungal meningitis outbreak.[11] As a result of his criminal conduct, Mr. Cadden | **Disputed**.<br><br>Misstates the record and omits facts necessary to provide context.<br><br>This is an issue on which, if relevant, Box Hill has the burden of proof and persuasion. The allegation is not supported by sufficient evidence and therefore is disputed. Moreover, as to claims concerning Box Hill patient |

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| was subsequently sentenced to nine years in prison.[12]<br><br>_____<br><br>[12] Pharmacist in meningitis outbreak that kills dozens gets 9 years in prison, BOSTON GLOBE (June 26, 2017), https://www.bostonglobe.com/metro/2017/06/26/feds-cadden-should-pay-for-fungal-meningitis-outbreak/kwet31ZTnsT4lpq4WRzkXO/story.html | deaths, Mr. Cadden was exonerated by the jury.[22*]<br><br>_____<br><br>[22*] *Pharmacist in meningitis outbreak that kills dozens gets 9 years in prison*, Boston Globe (June 26, 2017), *available at* https://www.bostonglobe.com/metro/2017/06/26/feds-cadden-should-pay-for-fungal-meningitis-outbreak/kwet31ZTnsT4lpq4WRzkXO/story.html. |
| 11. In the summer and fall of 2012, NECC failed to fulfill its duty to accurately represent the safety and quality of its products to consumer and potential consumers and, in doing so, broke the law.[13]<br><br>_____<br><br>[13] *See* Deposition Transcript of Dr. Lloyd R. Saberski, 65:5–65:18, excerpts attached as **Exhibit 7**. | **Disputed**.<br><br>Dr. Bhambhani never relied on any statement made by NECC in making her decision to purchase and inject its MPA into her patients.[23*]<br><br>Box Hill's contention also calls for a legal conclusion on an issue on which, if relevant, Defendants have the burden of proof and persuasion. The allegation is not supported by sufficient evidence to meet Defendants' burden.<br><br>_____<br><br>[23*] Ex. 7 at 99:23-100:11; 105:6-106:3. |
| 12. NECC's actions fell below the standard of care with regard to the contaminated lots of MPA.[14]<br><br>_____<br><br>[14] *See* Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 9** | **Disputed.**<br><br>Misstates the record and omits facts necessary to provide context.<br><br>Although NECC produced contaminated lots of PF MPA and violated the law, Box Hill was complicit with respect to purchasing multiple batches based upon false prescriptions.[24*]<br><br>Whether NECC's conduct also fell below the standard of care applicable to a pharmacy is an issue which, if relevant, and if the probative value outweighs possible prejudice to |

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| | Plaintiffs, Box Hill will have the burden of proof and persuasion. Box Hill's allegation is also vague, ambiguous, and unsupported by sufficient evidence.<br><br>[24*] Ex. 2 at 174:2-21, Ex. 5 at 166:20-168:2. |
| 13. The Box Hill Defendants' procurement of medications from NECC without using patient-specific prescriptions had no effect on whether the medications received were contaminated.[15] Plainly stated, using patient-specific prescriptions would not have prevented Plaintiffs' injuries.[16]<br><br>[15] *See* Deposition Transcript of Dr. Lloyd R. Saberski, 167:13–168:16, excerpts attached as **Exhibit 7**.<br><br>[16] *See id.* | **Disputed**. Misstates the crux of the claims, as explained in Plaintiff's response to Box Hill's ¶1 *supra*.<br><br>Box Hill's submission of fraudulent, bogus patient subscriptions to obtain office supplies of NECC's MPA was how the contaminated MPA was present in Box Hill's rural Maryland Clinic and eventually administered into Plaintiffs' bodies. Box Hill also administered medications labeled, and therefore legally intended, for patients other than those it administered to, such as Plaintiffs. Regulatory patient-specific prescription requirements, such as Massachusetts' and Maryland's, are safety mechanisms intended to protect patients from improper prescriptions as well as against being administered medications dispensed for others and not intended to be administered to them.<br><br>Plaintiffs will prove that the flaunting of rules and regulations by NECC was an indicator that NECC was mass compounding substances without the oversight of FDA and thus, based upon then available studies and information, presented an increased risk of contamination that should have resulted in her purchasing MPA from an FDA approved manufacturer.<br><br>Furthermore, because her knowledge base was substandard, Dr. Bhambhani did not appreciate that complying with NECC's procedure of providing false prescriptions for compounded MPA was not only substandard on her part, but violated laws regarding obtaining compounded medications for her patients. It |

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| | also caused an obvious red flag about NECC's suitability to make and supply MPA for her patients.<br><br>Further, Dr. Bhambhani used names of past treated patients to purchase 5 ml. single use vials that she then used on multiple patients for which the medication was not ordered, further increasing the risk to Plaintiffs of serious injury and death.[25*]<br><br>_____<br><br>[25*] Ex. 1 at 3, Ex. 2 at 78:3-79:12; 86:20-90:15; 102:11-111:21; 136:9-137:2; 153:3-13; 169:9-16; 182:13-185:2, Ex. 5 at 154:5-156:21; 158:1-23; 163:19-164:16; 166:20-168:10, Ex. 6 at 2; 3-4. |
| 14. The conduct of NECC, rather than the Box Hill Defendants, caused the MPA to be contaminated.[17]<br><br>_____<br>[17] *See id*., 64:7–65:1, excerpts attached as **Exhibit 7**. | **Disputed**.<br><br>Whether NECC's conduct was the sole cause of the MPA contamination (and injuries to Plaintiffs) is an issue on superseding causation on which Box Hill will have the burden of proof and persuasion, if relevant. The allegation is also unsupported by sufficient evidence.<br><br>Moreover, it is immaterial and irrelevant to the question of whether Box Hill Defendants are entitled to summary judgment as it ignores the evidence that absent Dr. Bhambhani's failure to comply with the minimum standard of care regarding the selection, storage, and use of MPA, her patients never would have received the contaminated product compounded by NECC and sustained their respective injuries.[26*]<br><br>_____<br><br>[26*] Ex. 1 at 5, Ex. 2 at 59:12-20; 66:16-20; 78:3-81:1; 79:13-80:5; 86:5-89:3; 96:22-97:14; 99:3-15; 102:11-103:10; 109:13-111:21; 112:9-113:20; 118:3-13; 121:19-122:9; 170:171:19, Ex. 5 at 229:24-230:8; |

| Box Hill's Alleged Undisputed Material Facts and Purported Supporting Evidence[1] | Plaintiffs' Reponses and Evidentiary Support[2] |
|---|---|
| | 175:20-177:9; 178:19-179:1; 207:7-208:8, Ex. 6 at 2. |
| 15. NECC's actions were both the actual and proximate cause of the injuries suffered by Plaintiffs.[18]<br><br>_____<br>[18] *See* Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 9**. | **Disputed**.<br>This is an issue on which, if relevant, Box Hill has the burden of proof and persuasion. Box Hill's allegation is also vague and ambiguous as well as unsupported by sufficient evidence. To the extent it is question of law, the statement is a misstatement of the record. Moreover, it is immaterial and irrelevant to the question whether Box Hill Defendants are entitled to summary judgment.<br>Had Dr. Bhambhani complied with the minimum standard of care regarding the selection, storage and use of MPA for her patients they never would have received the contaminated product compounded by NECC and sustained their respective injuries.[27*]<br><br>_____<br>[27*] *Id.* |

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, Michael Coren, hereby certify that a copy of the foregoing document, filed through the CM/ECF system will be accessible to those attorneys who are registered with the Court's electronic filing system and Notice of Electronic filing (NEF), including the attorneys representing the defendants in the above-referenced individual cases, and will be sent to these parties by operation of the CM/ECF system.

Dated: October 16, 2017

/s/ *Michael Coren*
Michael Coren